

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5720.3

2/13/09

COMPREHENSIVE REVIEW METHODOLOGY OF STATE MEAT AND POULTRY INSPECTION PROGRAMS

I. PURPOSE

This directive provides Federal State Audit Branch (FSAB) personnel in the Office of Program Evaluation Enforcement and Review (OPEER) and other staff involved in performing comprehensive reviews of State Cooperative Meat or Poultry Inspection (MPI) programs with the methodology and guiding principles for use in these reviews. The purpose of these reviews is to determine whether a State has developed and is maintaining a meat or poultry inspection program that imposes requirements “at least equal to” those imposed by FSIS under specified provisions of the Federal Meat Inspection Act (FMIA) and the Humane Methods of Slaughter Act (HMSA) or the Poultry Products Inspection Act (PPIA). The reviews also determine whether State Cooperative MPI programs are adhering to Federal civil rights laws and applicable USDA civil rights regulations, and whether they conform to the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

NOTE:- FSIS published “*At Least Equal*” To Guidelines for State Meat and Poultry Cooperative Inspection Programs (July 2008) to assist the State Cooperative MPI programs in establishing and maintaining inspection programs that are at least equal to the Federal inspection requirements. The guidelines can be found at

http://www.fsis.usda.gov/PDF/At_Least_Equal_to_Guidelines.pdf.

Key Points Covered

- *FSIS’s policy and procedures for comprehensive reviews of State Cooperative MPI programs*
- *Criteria FSIS uses to determine whether State Cooperative MPI programs are at least equal to the Federal inspection program.*

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.)
Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.)
Agriculture Marketing Act of 1946, as amended (7 U.S.C. 1621, et seq.)
Humane Methods of Slaughter Act 1978 (7 U.S.C. 1901-1906)
Title VI of the Civil Rights Act of 1964 (42 U.S.C. 200(d))
Section 504 of the Rehabilitation Act of 1973, as Amended (29 U.S.C. 794)
Age Discrimination Act of 1990 (42 U.S.C. 12101, et seq.)
9 CFR 306.5 (Appeals)
FSIS Directive 1090.1, Management Controls
FSIS Directive 1510.1, Equal Opportunity Notification on Material for the Public
FSIS Directive 1510.2, Civil Rights Compliance and Enforcement
FSIS Directive 3300.1, Fiscal Guidelines for Cooperative Inspection Programs
FSIS Directive 5710.1, Designation of States for Federal Meat or Poultry Inspection
FSIS Directive 6900.1, Humane Handling of Disabled Livestock
FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock
"At Least Equal to" Guidelines for State Meat and Poultry Cooperative Inspection Programs

V. BACKGROUND

A. The Federal Meat Inspection Act (FMIA) (21 USC 661) and the Poultry Products Inspection Act (PPIA) (21 USC 454) provide for FSIS to cooperate with State agencies in developing and administering State Cooperative MPI programs. Individual State Cooperative MPI programs need to operate in a manner and with authorities that are at least equal to the programs that FSIS has implemented under the ante mortem and postmortem inspection, reinspection, sanitation, record keeping, and enforcement provisions of the FMIA and PPIA. State Cooperative MPI programs are also expected to ensure that livestock are treated humanely by imposing humane handling requirements that are at least equal to those FSIS has established under the Humane Methods of Slaughter Act of 1978 (HMSA)(7 USC 1901-1906).

B. The jurisdiction of a State Cooperative MPI program is limited to product that is produced and sold within the State.

C. The "at least equal to" standard requires that State Cooperative MPI programs operate in a manner that is at least as effective as the Federal inspection program. The statutes do not require that the States operate their MPI programs in a manner that is the same as or identical to the FSIS program, nor

do they prohibit the State Cooperative MPI Programs from establishing safeguards that they believe to be more effective than those employed by FSIS.

D. If a State fails to administer a meat or poultry inspection program that is at least equal to the program that FSIS has established under the applicable provisions of the FMIA and HMSA or PPIA, FSIS will move to “designate” the State in accordance with 21 USC 661 (c) and 454 (c).

E. Under the FMIA and PPIA, FSIS may contribute up to 50% of the estimated total cost of the State’s Cooperative Inspection program and provide administrative support as long as the State is operating and maintaining a program that is “at least equal to” the Federal inspection program (21 U.S.C. 661 (a) (3) & 454 (a) (3)).

F. The FMIA and PPIA provide for FSIS to conduct at least annual reviews of State Cooperative MPI programs and their requirements, including enforcement of those requirements, with respect to slaughter, preparation, processing, storage, handling and distribution of livestock carcasses and parts, meat and meat food products of such animals, or poultry products (21 USC 661 (c) (4); 21 USC 454 (c) (4)).

G. A FSIS comprehensive review of a State’s Cooperative MPI program consists of two parts: (1) an annual review of the State Cooperative MPI program’s self-assessment submission; and (2) an on-site review to observe the State MPI program and to verify the accuracy of the State Cooperative MPI program’s self-assessment submission. Through the on-site and annual reviews, FSIS determines whether the State Cooperative MPI program is at least equal to the Federal inspection program. FSIS schedules on-site reviews of each State Cooperative MPI program at a minimum of once every three years.

H. Each year, FSIS makes an at least equal to determination on each State Cooperative MPI program. If the State Cooperative MPI program is not scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of the self-assessment review. If the State Cooperative MPI program is scheduled for an on-site review during the fiscal year, FSIS makes an annual determination based on the results of both the self-assessment and the on-site review.

VI. COMPREHENSIVE REVIEW METHODOLOGY AND CRITERIA

The FSIS review team, with staff from the Civil Rights Division (CRD, OM), the Financial Review and Analysis Branch (FRAB, OM), and FSAB, OPEER, evaluates each State Cooperative MPI program to determine whether it meets the “at least equal to” criteria for the following nine components:

1. Statutory Authority and Food Safety Regulations – State Cooperative MPI programs operate under laws and regulations that grant legal authority at

least equal to that provided under the FMIA and HMSA or PPIA.

2. Inspection – State Cooperative MPI program personnel perform inspection activities to verify whether establishments comply with applicable regulations and take appropriate enforcement actions when establishments are not in compliance with provisions that are at least equal to those adopted by FSIS.

3. Product Sampling – State Cooperative MPI program personnel samples meat or poultry products to verify whether they are free of adulterants (e.g., *E. coli* O157:H7 in non-intact, raw beef products, *Listeria monocytogenes* in ready-to-eat products or, drug residues at violative levels).

4. Staffing and Training – State Cooperative MPI programs provide competent inspection coverage in each establishment on days the establishment produces products that, if found to be not adulterated, are to bear the State mark of inspection.

5. Humane Handling – State Cooperative MPI program personnel perform regulatory verification procedures to assess whether establishment personnel humanely handle all livestock and take appropriate regulatory actions in response to noncompliance.

6. Non-Food Safety Consumer Protection – State Cooperative MPI program personnel perform verification procedures to confirm that meat and poultry products are wholesome, not economically adulterated, truthfully labeled, and meet the non-food safety regulatory requirements. State Cooperative MPI program personnel take appropriate actions in response to noncompliance.

7. Compliance – State Cooperative MPI program personnel perform surveillance activities with respect to meat or poultry products in intrastate commerce and take appropriate enforcement actions in the event that adulterated or misbranded products enter intrastate commerce.

8. Civil Rights – State Cooperative MPI programs adhere to Federal civil rights laws and USDA civil rights regulations.

9. Financial Accountability – State Cooperative MPI programs conform with 7 CFR 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments and follow FSIS Directive 3300.1, Rev. 2.

VII. SELF-ASSESSMENT REVIEW

A. FSIS expects State Cooperative MPI programs to submit self-assessments to FSIS by November 15th of each year. The FSIS review team (described in section VI above) is to verify that the State's annual self-assessment submission

demonstrates that the State Cooperative MPI program is “at least equal to” the Federal inspection program (e.g. laws, rules, policies, procedures, programs), and that it includes evidence and documentation that support that the processes are in effect and current with FSIS policies.

B. The review team is to verify that the State Cooperative MPI program has control measures in place to substantiate that its program is functioning as intended.

C. The review team is to begin its review with the State’s self-assessment submission from the previous year. The previous year’s self-assessment submission serves as a baseline for the current year.

NOTE: States are to submit any changes that they made to their Cooperative MPI programs during the previous 12 months and provide evidence and documentation that, as a result of those changes, the State’s Cooperative MPI program is current with FSIS statutes, regulations, and policies.

D. The review team is to request clarifying information from a State Cooperative MPI program if questions arise during the self-assessment review, or if more information is needed before a determination as to whether the State Cooperative MPI program is at least equal to the Federal inspection program can be made.

E. The review team is to verify that the State Cooperative MPI program completed and submitted the following documents, as provided for in the “*At Least Equal To*” *Guidelines for State Meat and Poultry Cooperative Inspection Programs* in the course of the Annual State Self-Assessment Review:

1. Annual Certification “at least equal to” the Federal Meat and Poultry Inspection Program
2. Annual Statement of Defensible Laboratory Results
3. State Laboratory Activity Table
4. State Establishment Profile
5. State Assignment and Employment Report
6. Compliance Activity Report
7. Certification Statement for Component 9

VIII. ON-SITE REVIEWS

A. Before traveling to the on-site review locations, the review team is to begin

preparation for the on-site review with a thorough review of the State Cooperative MPI program's most recent self-assessment submission.

B. At least 30 days before the scheduled start of the review, the review team leader is to send written notification to the Director of the State Cooperative MPI program to announce the scheduled dates for the forthcoming on-site review.

C. Prior to traveling to the on-site review location, at a time State Cooperative MPI program officials and the review team agree to, the review team is to conduct an entrance meeting teleconference with State Cooperative MPI program officials to introduce the team members to the State MPI officials that they will work with during the review. The team leader is to explain the review process to the participants and is to request that the State Cooperative MPI program submit the following information within 10 business days of the teleconference:

1. Descriptions of any changes that occurred in the MPI program since the most recent self-assessment submission;

2. A current list of establishments receiving inspection from the State Cooperative MPI program;

3. A description of each State field supervisor's area of responsibility;

4. The Hazard Analysis and Critical Control Point (HACCP) processing categories for each state-inspected establishment and a ranking of the highest volume producers for each HACCP processing category;

5. A list of all State-inspected establishments that the State Cooperative MPI program has reviewed within the previous 12 months;

6. A list of all State-inspected establishments that have had a history of any of the following within the preceding 12 months:

- a. Positive sample results for pathogens (e.g., *E. coli* O157:H7 in non-intact, raw beef products; *Listeria monocytogenes*, *Salmonella* or *E. coli* O157:H7 in ready-to-eat products);

- b. *Salmonella* verification sample set results that exceed the performance standard or guideline established by FSIS;

- c. Enforcement actions;

- d. Recalls; and

- e. Structural damage to State-inspected establishments caused by a

natural or other disaster.

D. The review team is to select the total number of establishments for the onsite review using a statistically valid sampling method.

E. After determining the total number of establishments for the onsite review, the review team is to select specific establishments for review based on adverse public health risks identified in C (6) above, including at least three establishments that the State Cooperative MPI program has reviewed during the preceding 12 months.

F. The review team is to provide State Cooperative MPI program officials with a list of the selected establishments at least five working days before the on-site review.

G. The review team is to begin each establishment review with an entrance meeting with State Cooperative MPI program officials and establishment management to explain the purpose and methodology for the review.

H. During the establishment reviews, the review team member doing the review of how the inspection program is operating is to observe State Cooperative MPI program officials executing the State Cooperative MPI program.

I. At each establishment, this review team member is to review the State Cooperative MPI program's verification of compliance with applicable State requirements on Sanitation Standard Operating Procedures (SOPs), HACCP, non-food safety related consumer protection, control of specified risk materials, humane handling, or custom exempt/retail exempt requirements.

J. This review team member is also to observe State Cooperative MPI program inspectors as they perform ante-mortem and post-mortem inspection procedures.

K. Based on observation and records review, this review team member is to document on FSIS Form 5000-9 any establishment noncompliance that the State Cooperative MPI program has failed to recognize or for which the State Cooperative MPI program has failed to take an appropriate regulatory action.

L. At the conclusion of each establishment on-site review, this review team member is to report the findings to the State Cooperative MPI program officials.

M. This review team member is to observe the State Cooperative MPI program officials as they lead the exit conference with plant management and discuss the findings of each establishment on-site review, including any noncompliances identified.

N. Before leaving an establishment, this review team member is to ensure

that the State Cooperative MPI program officials have taken appropriate actions with respect to all noncompliances observed during the establishment review.

O. After completion of the establishment reviews, a review team is to review documents at the State Cooperative MPI program office to determine whether the results of the review support a determination that the State Cooperative MPI program is at least equal to the Federal inspection program with respect to product sampling, staffing, training, and compliance, and that the State Cooperative MPI program has an internal control system that identifies and addresses risks and ensures the program is functioning as intended.

P. After the on-site review of State establishments and the review of documentation at the State offices, the review team is to analyze all information gathered during the reviews and identify program findings. Program findings are both independent results of the on-site review, as well as the comparison of the on-site review results with the State Cooperative MPI program's operations and records. The review team's findings are to focus on implementation of food safety policy and procedures. The review team's evaluation is to focus on evaluating whether the program meets the criteria for the nine components detailed in Section VI.

Q. The review team leader is to:

1. Schedule an exit meeting with State Cooperative MPI program officials within ten business days after completion of the on-site review.
2. Present the program findings to State Cooperative MPI program officials at the scheduled exit meeting.
3. Request that the State Cooperative MPI program officials submit an action plan to correct all program findings identified during the review within ten business days of the date of the exit conference.
4. Explain to the State Cooperative MPI program officials that the State's action plan needs to:
 - a. identify the underlying causes of the program findings that may be system-wide and ensure that there is Statewide correction of such findings; and
 - b. identify the underlying causes of specific findings at individual establishments and ensure that the State MPI program verifies that the establishments address such findings.

IX. DETERMINATION PROCESS FOR "AT LEAST EQUAL TO" STATUS

A. Following each self-assessment and on-site review, FSIS is to make a

determination on each State Cooperative MPI program based on the “at least equal to” standard. FSIS is to make one of the following three determinations for each component listed in section VI and on the State’s overall ability to maintain its MPI program for the next 12 months.

1. “At Least Equal To” - The State Cooperative MPI program is based on, and has adopted and implemented, equivalent laws, regulations, and programs for all review components.

2. “Not At Least Equal To” – The State Cooperative MPI program is not based on, or has not enacted or implemented, equivalent laws, regulations, or programs for one or more of the review components.

3. “Deferred” – FSIS is unable to make a determination of the State Cooperative MPI program’s status because of the program’s inability to immediately implement corrective actions resulting from the comprehensive review findings.

B. If the determination of the self-assessment or of the on-site review is that the State Cooperative MPI program is at least equal to the Federal inspection program, FSAB will promptly notify the State Cooperative MPI program officials in writing of this fact.

C. If FSAB determines that it needs additional information from State Cooperative MPI program officials to reach a determination, it is to request the information from the State Cooperative MPI Program officials. In the event that a State Cooperative MPI program’s action plan cannot be implemented immediately, but the State is committed to making the corrections and has the resources to support the changes, then, on a case by case basis, FSAB may recommend to the Assistant Administrator of OPEER a deferral of the determination on the State Cooperative MPI program’s “at least equal to” status. FSAB is to perform a follow-up review to verify the State Cooperative MPI program’s effective implementation of its action plan.

D. If FSAB determines that a State MPI program is unable or unwilling to maintain an inspection program that is “at least equal to” the Federal inspection program, FSAB will notify the Assistant Administrator of OPEER, who will in turn notify the FSIS Administrator of this fact.

X. DATA ANALYSIS AND REPORTING

FSAB will develop an end-of-year report that summarizes the findings and final determinations for all State Cooperative MPI Programs, highlights of the components in Section VII with which States had difficulties complying, and sets out any other noteworthy findings. FSIS will post this report on the FSIS Web site.

Refer questions regarding this directive through supervisory channels.

A handwritten signature in black ink, appearing to read "Mary S. Dufle". The signature is fluid and cursive, with a long horizontal stroke at the end.

Assistant Administrator
Office of Policy and Program Development